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| APPLICATION NO.                                                  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------|-------------|-----------------------|---------------------|------------------|
| 09/936,668                                                       | 09/13/2001  | Jack Thatcher Leonard | MCA-448 PC/US       | 8911             |
| 25182                                                            | 7590        | 12/01/2003            | EXAMINER            |                  |
| MILLIPORE CORPORATION<br>290 CONCORD ROAD<br>BILLERICA, MA 01821 |             |                       | KIM, SUN U          |                  |
|                                                                  |             |                       | ART UNIT            | PAPER NUMBER     |

1723

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/936,668

Applicant(s)

LEONARD, JACK THACHER

Examiner

John Kim

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 4, 6, 11-14, 16, 18 and 22 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 7-10, 15, 17, 19-21 and 23-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Claims 1, 3, 5, 7-10, 15, 17, 19-21 and 23-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,223,133 (hereinafter referred to as Clark et al '133) in view of U.S. Patent No. 4,948,564 (hereinafter referred to as Root et al). Clark et al '133 teach a process for concentration of nucleic acids comprising the steps of providing ultrafiltration membrane (15) having a molecular cutoff between 1 00 D and 2000 kD and made of polysulfone in 25 multiple wells (11), processing a volume of up to 400 microliters i.e. 0 to 400 microliters of sample, subjecting the sample on the membrane to vacuum (5) till nucleic acids are concentrated on the membrane (see figures 1-3, 6-7; col. 3, lines 15-18; col. 3, line 60 – col. 4, line 36; col. 5, lines 28-61). Claims 1, 8, 10, 15, 17, 19-21, 23-24 and 27-29 essentially differ from the method of Clark et al '133 in reciting the step of applying a constant pressure differential. Clark et al '133 teaches that vacuum chamber (2) is connected to a regulated external vacuum source to apply vacuum to wells (11) through membrane (15) (see col. 3, line 60 – col. 4, line 11). Root et al teach the use of a valve (100) adjacent a vacuum passage to provide even pressure control across the filter membrane to avoid splattering of filtrate in vacuum chamber (70)(see figures 5-6; col. 6, lines 17-31). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a constant pressure differential to wells via a valve adjacent a vacuum passage to avoid splattering of filtrate in vacuum chamber of Clark et al '133. Regarding claims 3, 25-26, and 30, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to regulate pressure differential from 169 millibars to about 914 millibars to the wells of Clark et al '133 to obtain desired rate of ultrafiltration. Regarding claim 5, Root et al teach a positive pressure applied by a syringe (see col. 7, line 59 – col. 8, line 27). It would have been obvious to a person of ordinary skill in the art at the time the

invention was made to apply positive pressure from about 5 psi to about 80 psi to the wells of Clark et al '133 to obtain desired rate of ultrafiltration. Regarding claim 7, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a single well device to process a single sample. Regarding claims 9 and 31, Root et al teach that 96 well plate is widely used (see col. 1, lines 29-32). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a well-known 96-well filtration plate in the method of Clark et al '133 for concentrating nucleic acids.

2. Claims 2, 4, 6, 11-14, 16, 18 and 22 are allowed.
3. Applicant's arguments, see response, filed 9/8/03, with respect to the rejection(s) of claim(s) 1, 3, 5, 7-10, 15, 17, 19-21 under 102 and/or 103 rejection have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Clark et al '133 and Root et al.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

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**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
November 22, 2003